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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,920	02/01/2000	ARNE EEK	1103326-0603	6956

7470 7590 12/01/2003

WHITE & CASE LLP
PATENT DEPARTMENT
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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	20

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/463,920	Applicant(s) EEK ET AL.	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-32 and 35-40* is/are pending in the application.

4a) Of the above claim(s) *28-30,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-27, 31, 32, 35, 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, Amendment, and Request for Continued Examination filed 09/25/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/25/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-11, 14-18, 22-27, 31, 32, 38, and 39 are rejected as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place them in proper dependent form, or rewrite the claims in independent form. The transitional phrase "consisting essentially of" recites in claim 1 limits the dosage form to the basic structure, such as tablet and capsule. The phrase "dosage form consisting essentially of" does not include the enteric coating, coated pellet, or layer tablet.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 11-27, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. US 6,365,184, in view of Woolfe et al. US 6,387,410.

Depui teaches an oral composition comprising combination of NSAID and proton pump inhibitor, such as omeprazole, lansoprazole, pantoprazole, or salts thereof; carriers; and excipients (columns 5-8). The composition is useful for the treatment of gastrointestinal disorders (column 1, lines 10-18). The composition can be in the form of pellet, granules, coated pellet, compressed tablet, or capsule (columns 9-14). Depui does not teach combination of proton pump inhibitor and gastric antisecretory prostaglandin.

Woolfe teaches composition comprising combination of NSAID and prostaglandin, such as misoprostol (columns 1-3). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Depui's composition with the use of prostaglandin in view of the teachings of Woolfe, because Woolfe teaches the advantageous result in the use of misoprostol for the treatment of gastrointestinal side-effects associated with NSAID. The expected result would be a single dosage form comprising combination of proton pump inhibitor, NSAID, and prostaglandin for the treatment of gastrointestinal disorders.

Claims 1-4, 11-27, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akira Tari et al. (Digestive Diseases and Sciences, Vol. 42), and Depui et al.

Tari teaches omeprazole-enprostil combination useful for the treatment of peptic ulcer (pages 1744).

Akira is relied upon for the reason stated above. Although Akira teaches the combination of omeprazole-enprostil is orally administered (page 1742), Akira is silent as to the specific oral dosage form.

Depui teaches oral dosage form comprising omeprazole and NSAID in the form of pellet, granules, coated pellet, compressed tablet, or capsule (columns 9-14). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Akira's composition as an oral dosage form of Depui, because controlled/sustained release oral dosage is useful for the treatment of gastrointestinal disorders.

Claims 1-4, 6-27, 31, 32, 35, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. in view of Woolfe et al., and Shell US 5,582,837.

Depui and Woolfe are relied upon for the reasons stated above. The references are silent as to the teachings of the use of calcium channel blocker.

Shell teaches sustained release dosage form containing calcium channel blockers useful for the treatment of gastric diseases (columns 3-4). Hence, it would have been prima facie obvious for one of ordinary skill in the art to prepare composition of Depui and Woolfe with calcium channel blocker in view of the teaching of Shell,

because the references teaches the advantageous result of oral formulation useful for treating gastrointestinal disorders. The expected result would be a single dosage form comprising combination of proton pump inhibitor, NSAID, calcium channel blocker, and prostaglandin for the treatment of gastrointestinal disorders.

Response to Arguments

Applicant's arguments filed 09/25/03 has been fully considered but they are not persuasive.

Claim 30 was inadvertently rejected under 112, 2nd paragraph in the last office action. Claim 30 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (see paper No. 10, dated 07/17/02).

Applicant argues that claim 1 has been amended to include the transitional phrase "consisting essentially of" to exclude additional unspecified ingredients, which would affect the basic and novel characteristics of the invention defined in the balance of the claim. Thus, the patentable feature of claim 1 is the combination of an ATP-ase inhibitor and prostaglandin in a single dosage form, and therefore, the combination of Depui and Woolfe; or the combination of Akira Tari and Depui et al., does not suggest the claimed invention since the references disclosed the use of NSAIDs. However, absent a clear indication in the specification of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ at 1355. From a reading of applicant's original specification, it is clear that 1) applicant did not intend to exclude NSAIDs of the

prior art, and 2) that the prior art NSAIDs are clearly not detrimental. When an applicant contends that additional materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). Applicant's specification in page 20, lines 14-21, permits the use of calcium channel blocking agent, and NSAID, or other anti-ulcerative agents in combinations with the claimed invention. Thus, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to combine Depui and Woolfe, or Depui and Akira Tari. In response to applicant's argument regarding the examiner's conclusion of obviousness, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that the combination of Depui, Woolfe and Shell does not suggest the claimed invention because the amended claim excludes an NSAID. For the above disclosed reasons regarding to the transitional phrase "consisting essentially of", it is the examiner's position that the combination of Depui and Woolfe, and Shell does suggest the claimed invention. In response to applicant's argument regarding the examiner's conclusion of obviousness, it must be recognized that any judgment on

obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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